

**REMARKS**

Claims 112-163 were pending in the present application. Claims 102-122, 124-127, 132-135, 139-142, and 152-163 have been withdrawn from consideration. Claims 112, 116, 123, 128, 129, 138, 146, and 149 have been amended herein. No new matter has been added. Upon entry of the present amendment, claims 112-163 will remain pending.

An amended Sequence Listing is provided herewith as requested by the Examiner.

**I. The Claimed Invention Is Useful**

Claims 112-117, 119, and 128 are rejected under 35 U.S.C. §101 as allegedly failing to claim non-statutory subject matter. Although Applicants disagree with the reasoning set forth in the Office Action, independent claims 112, 116 and 128 have been amended to further recite “isolated”, as suggested by the Examiner. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

**II. The Claims Are Clear And Definite**

Claims 123, 128-131, 138, 146, and 149 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Applicants respectfully request reconsideration and withdrawal of the rejection in view of the amendments to the claims and the comments presented below.

The Office Action asserts that claims 123, 128, and 129 are confusing by reciting “analogue” because “it is not clear whether the modification that renders this peptide an ‘analogue’ is within SEQ ID NO:1, or in a sequence adjacent thereto” (see, page 3 of the Office Action). Claims 123, 128, and 129 each recite that 1) the “analogue” is of a peptide comprising SEQ ID NO:1; 2) the “analogue” is capable of being recognised by a T cell receptor that recognises a peptide comprising SEQ ID NO:1; and 3) the “analogue” is not more than 50 amino acids in length. The question of whether the “modification” that renders the “analogue” to be an “analogue” is within SEQ ID NO:1 or an adjacent sequence is quite irrelevant to whether the claim is clear and definite. Indeed, persons of ordinary skill would have no difficulty in

determining whether a particular analogue meets the criteria recited in the claims. In fact, it makes no difference where the “modification” is located. Accordingly, the claims are definite within the meaning of §112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Thus, claims 123, 128, and 129 are clear and definite.

The Office Action asserts that the preamble in claim 129 is unclear by claiming a “composition” as a Markush group. Although Applicants disagree, solely to advance prosecution, Applicants have amended claim 129 to delete “composition.”

Recitation of “the antibody-IFN- $\gamma$  complex” in claim 138 and “the antibody-cytokine complex” in claim 149 are alleged to lack antecedent basis. Although Applicants maintain that these two phrases are inherently present when the antibody to IFN- $\gamma$  or cytokine comes into contact with IFN- $\gamma$  or a cytokine, solely to advance prosecution, claims 138 and 149 have been amended to provide even more proper antecedent basis. No change in claim scope is intended.

The Office Action also asserts that recitation of “before determining in vitro” in claim 146 is unclear. Applicants have amended claim 146 to delete this phrase.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

### **III. The Claimed Invention Is Supported by Ample Written Description**

Claims 116-119, 128-131, 136-138, and 143-151 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse the rejection and respectfully request reconsideration because the specification provides ample written description supporting the claimed inventions.

The Office Action asserts that recitation of “and other/gliadin/non-gliadin sequence” in claims 116-118 without limiting the other sequence to one that is fused is new matter. The Office Action further asserts that only fusion proteins and not other types of polypeptides, such as

conjugates, are described in the specification. Merely because the specification points out one particular type of polypeptide (i.e., a fusion protein; see page 10, line 15, and page 22, line 10 of the specification), however, does not mean that other types of polypeptides are also not included. Indeed, original claim 3 recites that the agent can be an analogue that comprises SEQ ID NO:1 or 2, for example, **bound** to an HLA molecule. The term “bound” certainly does not conventionally mean only a “fusion” peptide, and certainly does not exclude conjugated peptides. Thus, Applicants were clearly in possession of a peptide comprising SEQ ID NO:1, for example, and other gliadin or non-gliadin sequences, regardless of whether the peptide is one formed by fusion of two peptides or conjugation of two peptides.

The Office Action also asserts that the specification fails to provide a description of SEQ ID NO:1 fused to another gliadin sequence as recited in claims 116, 117, 128, and 129. Applicants teach at, for example, page 11, lines 24-31 of the published international application that the agent can be a **product** that comprises at least two agents, one of which can be SEQ ID NO:1. The Abstract also teaches that the agent can be selected from a product comprising two or more agents “as defined in (i), (ii) or (iii).” Applicants also teach that the other agent can be selected from all of the gliadins present in any of the species or variety mentioned in the application. Applicants also teach at, for example, page 23, line 27 to page 24, line 5 of the published international application, polynucleotides which are capable of expression to provide the agent or mutant gliadin proteins. Applicants further teach that the polynucleotide therefore comprises sequences which encode SEQ ID NO:1, for example, “or any of the agents mentioned herein.” Thus, when taken together, Applicants teach a polynucleotide that is capable of expressing a product that comprises at least two agents, one of which is SEQ ID NO:1 and the other of which is any other gliadin. Such an expression product is a fusion protein.

The Office Action has taken the position that the “product” referred to in the specification is a composition comprising multiple agents. The Office Action has provided no reasoning or evidence, however, to indicate that the term “product” is limited to compositions while excluding a single compound. Indeed, the term “product” clearly may include both a single compound and a composition.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly failing to provide sufficient written description be withdrawn.

#### **IV. The Claimed Invention Is Sufficiently Enabled**

Claims 116, 117, 128-131, 136-138, and 143-151 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office Action mistakenly asserts that it would require undue experimentation for one skilled in the art to use the protein wherein SEQ ID NO:1 or SEQ ID NO:2 is fused to another gliadin sequence and that one skilled in the art would not know whether to use such a protein in diagnostic testing, as an immunization agent, or as a tolerizing agent. Applicants traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

As stated above, Applicants' specification provides ample description of SEQ ID NO:1 or SEQ ID NO:2 fused to another gliadin sequence. The abstract set forth on the cover page of the international application provides one use as a diagnostic for such an agent. For example, the abstract teaches that a method of diagnosing celiac disease by contacting a sample from the host with an agent. The agent can be SEQ ID NO:1, SEQ ID NO:2, or an equivalent sequence from a naturally occurring homolog of the gliadin having SEQ ID NO:3 (see part i). The agent can also be a product comprising two or more agents such as SEQ ID NO:1, SEQ ID NO:2, or an equivalent sequence from a naturally occurring homolog of the gliadin having SEQ ID NO:3 (see part iv). Thus, the specification teaches one skilled in the art to use a protein wherein SEQ ID NO:1 or SEQ ID NO:2 is fused to another gliadin sequence as, for example, a diagnostic.

Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation to make and use the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

**V. Conclusion**

The pending claims are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative at (215) 665-6914 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Paul K. Legaard", is written over a horizontal line.

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